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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/882,805	06/14/2001	Peter R. C. Gascoyne	UTXC:625US/MCB	7954

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EXAMINER	
BARTON, JEFFREY THOMAS	
ART UNIT	PAPER NUMBER
1753	

DATE MAILED: 10/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/882,805	Applicant(s) GASCOYNE ET AL.
Examiner Jeffrey T. Barton	Art Unit 1753

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 03 March 2003.
- 2a) This action is FINAL.
- 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-18 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-18 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 - 1. Certified copies of the priority documents have been received.
 - 2. Certified copies of the priority documents have been received in Application No. _____.
 - 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 20030303, 20021120
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-4, 6, 10-13, and 15-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Blankenstein.

Addressing the independent claims:

Regarding claim 1, Blankenstein discloses a method of separating matter using dielectrophoresis combined with magnetophoresis, comprising: injecting a sample into a chamber and initiating carrier medium flow at the inlet port (Page 18, lines 30-33), generating dielectrophoretic and magnetophoretic forces on the constituents (Page 8, lines 4-5; Page 9, lines 15-25; and Page 16, lines 1-15), balancing the dielectrophoretic and magnetic forces to position the constituents within the chamber (Page 5, line 29 - Page 6, line 3; Page 10, lines 31-38), and collecting the constituents at outlet ports according to their dielectric and magnetic characteristics. (Page 18, line 35 - Page 19, line 2)

Regarding claim 10, in addition to the disclosure cited above, Blankenstein discloses continuous-mode separation by a method comprising continuous injection of

Art Unit: 1753

the sample (Page 11, lines 13-21) and collection of the constituents according to their position. (Figure 1)

Regarding claim 13, in addition to the disclosure cited above, Blankenstein discloses a method comprising: providing a chamber with an inlet and outlet, an array of electrodes, and one or more permanent magnets configured to generate a magnetic force in the chamber. (Figure 3; Page 10, lines 31-33)

Regarding claim 15, in addition to the disclosure cited above, Blankenstein discloses a method comprising labeling a sample with labels having dielectric and magnetic properties, the labels combining with sample components (Page 18, lines 22-25; Page 9, lines 15-25); providing signals to the electrodes and magnetic elements to generate fields in the chamber (Page 9, lines 15-25; Page 10, lines 31-33); continually injecting the sample into an inlet port (Page 11, lines 13-21) and collecting the constituents with similar properties at the same outlet port according to their position. (Figure 1)

Regarding claim 16, Blankenstein discloses an apparatus comprising a chamber having inlets and outlets (Figure 1); an array of electrodes for generating a dielectrophoretic force on samples in the chamber (Figure 3; Page 10, lines 31-33); an array of magnetodes configured to generate a magnetic force on samples in the chamber (Page 8, lines 7-25); with the electrodes and magnetodes configured to generate forces that balance each other and displace constituents within the sample according to dielectric and magnetic properties. (Page 8, line 4 - Page 9, line 25; Page 16, lines 1-16; Page 10, lines 31-33)

Addressing the dependent claims:

Regarding claims 2 and 11, Blankenstein discloses the sample comprising analytes mixed with labels having magnetic and dielectric properties. (Page 18, lines 22-25; Page 10, lines 15-25)

Regarding claims 3 and 12, Blankenstein discloses the sample comprising plural labels (Page 18, lines 22-25; Page 10, lines 15-25; more than one bead will be present - claim does not limit to *different* first and second properties)

Regarding claim 4, Blankenstein discloses constituents traveling at velocities dependent on their positions in the chamber. (Page 5, line 29 - Page 6, line 3; Page 22, lines 2-4; Page 6, line 33 - Page 7, line 5; varying position in laminar flow system will lead to varying velocities)

Regarding claim 6, Blankenstein discloses collecting constituents with different properties emerging at different positions from plural outlet ports. (Page 8, lines 27-36)

Regarding claim 17, Blankenstein discloses the magnetodes comprising permanent magnets. (Page 8, line 7)

Regarding claim 18, Blankenstein discloses the outlet port comprising multiple ports for collecting bands of fluid that travel through the chamber at defined positions. (Page 8, lines 27-36)

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 1753

6. Claims 5, 7-9, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blankenstein in view of Jiang et al.

Addressing claim 5:

Blankenstein discloses a method as disclosed above in addressing claim 1.

Blankenstein does not explicitly disclose a method comprising collecting different constituents emerging at different times from the outlet ports.

Jiang et al disclose a field flow fractionation device of similar design (i.e. inlets, outlets, chamber with field-application means for causing separation; Figures 1a and 1b) which uses magnetophoresis and/or dielectrophoresis to cause separation of components (Columns 1 and 2) that are collected as they emerge at different times from the outlet port, based on magnetic and/or dielectric properties. (Figures 6-9)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Blankenstein by performing an analysis in batch mode to utilize differential velocities in the separation, as taught by Jiang et al, because it would provide additional analytical data based on elution time. (e.g. mass, polarizability, magnetic susceptibility)

Addressing claims 7-9:

In addition to the disclosure cited above for claim 1, Blankenstein discloses flow that causes the constituents to travel at velocities dependent upon their positions in the

Art Unit: 1753

chamber (Page 5, line 29 - Page 6, line 3; Page 22, lines 2-4; Page 6, line 33 - Page 7, line 5; varying position in laminar flow system will lead to varying velocities)

Regarding claim 8, Blankenstein discloses the sample comprising analytes mixed with labels having magnetic and dielectric properties. (Page 18, lines 22-25; Page 10, lines 15-25)

Regarding claim 9, Blankenstein discloses the sample comprising plural labels (Page 18, lines 22-25; Page 10, lines 15-25; more than one bead will be present - claim does not limit to *different* first and second properties)

Blankenstein does not explicitly disclose injection of a sample aliquot, or collecting constituents according to time-of-exit from an outlet port in a batch-mode run.

Jiang et al disclose a field flow fractionation device of similar design (i.e. inlets, outlets, chamber with field-application means for causing separation; Figures 1a and 1b) which uses magnetophoresis and/or dielectrophoresis to cause separation (Columns 1 and 2) of components of a sample aliquot (Column 19, lines 20-24) that are collected as they emerge at different times from the outlet port, based on magnetic and/or dielectric properties. (Figures 6-9)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Blankenstein by performing an analysis in batch mode to utilize differential velocities in the separation, as taught by Jiang et al, because it would provide additional analytical data based on elution time. (e.g. mass, polarizability, magnetic susceptibility)

Addressing claim 14:

In addition to the disclosure cited above for claim 1, Blankenstein discloses a method comprising labeling a sample with labels having dielectric and magnetic properties, the labels combining with sample components (Page 18, lines 22-25; Page 9, lines 15-25); providing signals to the electrodes and magnetic elements to generate fields in the chamber (Page 9, lines 15-25; Page 10, lines 31-33); and using the flow to cause the analytes and complexes to travel at velocities dependent upon their positions within the channel (Page 5, line 29 - Page 6, line 3; Page 22, lines 2-4; Page 6, line 33 - Page 7, line 5; varying position in laminar flow system will lead to varying velocities)

Blankenstein does not explicitly disclose a method comprising collecting the analyte-label complexes having similar properties in a single elution peak.

Jiang et al disclose a field flow fractionation device of similar design (i.e. inlets, outlets, chamber with field-application means for causing separation; Figures 1a and 1b) which uses magnetophoresis and/or dielectrophoresis to cause separation (Columns 1 and 2) of components of a sample aliquot that are collected as they emerge from the outlet port, based on their magnetic and/or dielectric properties, with similar components detected as single peaks. (Figures 6-9)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Blankenstein by performing an analysis in batch mode to utilize differential velocities in the separation and collect separated components as peaks of similar substances, as taught by Jiang et al, because it would

provide additional analytical data based on elution time. (e.g. mass, polarizability, magnetic susceptibility)

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-4, 6, 10-13, and 15-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 17 of U.S. Patent No. 6,790,330 in view of Blankenstein.

Claim 17 of U.S. Patent No. 6,790,330 claims a method of cell isolation comprising introducing the cells into a chamber, generating dielectrophoretic and magnetic forces on the particles to be separated, balancing the dielectrophoretic force with a gravitational force, providing carrier fluid flow (needed for velocity profile) and collecting the constituents at the outlet.

Claim 17 of U.S. Patent No. 6,790,330 does not explicitly require balancing the dielectrophoretic and magnetic forces.

Blankenstein discloses a similar separator that involves balancing of dielectrophoretic and magnetic forces in the chamber. (See treatment of claim 1, above) He also discloses separation of more general types of matter, as in Claim 17 of U.S. Patent No. 6,790,330 (Abstract). Blankenstein also discloses the limitations of the other listed claims.

It would have been obvious to one having ordinary skill in the art to modify the method claimed by claim 17 of U.S. Patent No. 6,790,330 by balancing the dielectrophoretic and magnetic forces, as taught by Blankenstein, because it would allow a controllable separation. It would also have been obvious to use such a method to separate any particles (i.e. matter) susceptible to such forces.

Furthermore, it would also have been obvious to modify the method claimed by Claim 17 of U.S. Patent No. 6,790,330 by incorporating the other limitations of the

instant claims, also taught by Blankenstein, because they are known variations within the field of dielectrophoretic and magnetophoretic separations of biological materials.

9. Claims 5, 7-9, and 14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 17 of U.S. Patent No. 6,790,330 in view of Blankenstein and Jiang et al. The disclosed material and motivations for combination are analogous to those given above in paragraphs 6 and 8.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hofmann discloses fractionation using simultaneous dielectrophoretic and magnetophoretic forces. Wilson discloses magnetic particles for biological applications with differing magnetic properties.

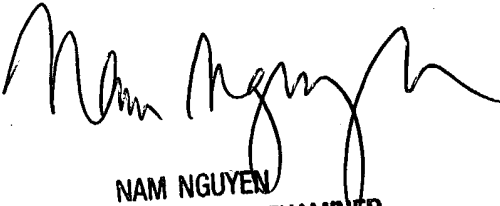
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Jeffrey Barton, whose telephone number is (571) 272-1307. The examiner can normally be reached Monday-Friday from 8:30 am – 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached at (571) 272-1342. The fax number for the organization where this application or proceeding is assigned is (703) 872-9306.

Art Unit: 1753

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

JTB
October 21, 2004.



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